

REMARKS

I. Status of the Application

Claims 25-27, 29-38, 40-43, and 47-52 are pending in the application. Claims 28, 39, and 44-46 have been cancelled without prejudice to the filing of any appropriate continuation applications. Claim 25 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 25, 27, 29, 32-34, 37, 40, and 48-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky et al. (U.S. Patent No. 4,141,783, hereinafter “Pisecky”) in view of Badertscher (GB 2 036 534), Den Hollander (U.S. Patent No. 5,558,819), Scott et al. (U.S. Patent No. 3,925,560, hereinafter “Scott”), and further in view of ehow.com (How to Prepare a Ready-to-Mix Powdered Baby Formula internet printout).

Claims 26, 30, and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Rubens (EP 0 438 783).

Claims 35 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Arndt (U.S. Patent No. 3,843,828).

Claims 38 and 41 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Bond et al. (U.S. Patent No. 5,210,958, hereinafter “Bond”).

Claim 42 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, Bond, and further in view of Hovmand et al. (U.S. Patent No. 4,062,641, hereinafter “Hovmand”).

Claim 43 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Johnston (U.S. Patent No. 2,401,077).

Claim 47 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Bosund et al. (U.S. Patent No. 4,091,003, hereinafter “Bosund”).

Applicant has amended the claims under consideration to more clearly define and distinctly characterize Applicant's novel invention. Specifically, independent claim 25 has been amended to recite the step of drying the pasteurized or sterilized product. Support for this amendment can be found throughout the specification as filed, for example at page 8, lines 14-17 and at page 11, lines 9-14 (which discloses drying of the pasteurized or sterilized product). Claim 25 was also amended to consistently recite a "pasteurized or sterilized product." Claim 25 has also been amended to delete the reference to particle size, as Applicant does not believe that this subject matter is required for patentability.

Applicant respectfully submits that the amendments presented herein do not raise new issues requiring further search, and add no new matter. Applicant respectfully requests entry and consideration of the foregoing amendments in view of the following remarks, which are intended to place the case in condition for allowance.

II. Claim 25 Is Definite

At page 2, section 2 of the instant Office Action, independent claim 25 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner is of the opinion that the limitation "wherein after drying" lacks antecedent basis in the claim. Applicant has amended claim 25 to recite the step of drying the pasteurized or sterilized product. Thus, claim 25 now has antecedent support for "wherein after drying." Accordingly, Applicant respectfully requests withdrawal of the § 112, second paragraph rejection and allowance of claim 25.

III. The Pending Claims Are Nonobvious over the Cited Art

At page 2, section 5 of the instant Office Action, claims 25, 27, 29, 32-34, 37, 40, and 48-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, and further in view of ehow.com. At page 6, section 6 of the instant Office Action, claims 26, 30, and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Rubens. At page 7, section 7 of the instant Office Action, claims 35 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Arndt. At page 8, section 8 of the

instant Office Action, claims 38 and 41 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Bond. At page 9, section 9 of the instant Office Action, claim 42 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, Bond, and further in view of Hovmand. At page 9, section 10 of the instant Office Action, claim 43 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Johnston. At page 10, section 11 of the instant Office Action, claim 47 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pisecky in view of Badertscher, Den Hollander, Scott, ehow.com, and further in view of Bosund. Applicant respectfully traverses these rejections.

The pending claims are directed in part to a method for pasteurizing or sterilizing a product in liquid form which includes a heat sensitive substance comprising substantially **atomizing** the product in liquid form while admixing steam **in a mixing chamber**, wherein the residence time of the product (mixed with steam) in the mixing chamber is between about 0.2 msec and 20 msec. After the residence time, the pasteurized or sterilized product is then dried into powder form. Atomization of the product with steam inside the mixing chamber provides for rapid heat transfer from the steam to the product, which serves to pasteurize or sterilize the product during a heating or residence time in the mixing chamber much shorter than standard. A standard pasteurization treatment heats the product to 82 °C for 20 seconds, but will damage heat sensitive substances (specification page 4, lines 1-5). Standard UHT (ultra-high temperature) sterilization methods heat the product to above 135 °C for 2-5 seconds, but still causes flavor damage (please see Attachment A). The present invention has made it possible to reduce the time needed to pasteurize or sterilize to between about 0.2 and 20 msec.

Such a reduction in pasteurization or sterilization time is important to avoid subjecting the product to extended heating periods which decompose or otherwise chemically altering the heat sensitive substances in the product. In particular, one or more of the following may be substantially avoided or greatly reduced:

- Denaturation and polymerization of proteins,
- Inactivation of vitamins (e.g. due to degradation or other reactions),

- Reaction of protein hydrolysates with sugars, resulting in an undesired increase of the molecular weight of the hydrolysate,
- Occurrence of Maillard reactions, which generally cause a loss of nutritional value, undesired browning of the product, and/or formation of off-flavors,
- Degradation of polysaccharides such as starch, which may cause a partial loss of the thickening properties of such polysaccharides (overcooking/dextrinization),
- Formation of undesired by-products, such as lactulose and lysinoalanine.

A. The combination of Pisecky, Badertscher, Den Hollander, Scott, and ehow.com fails to render the claimed invention obvious.

The Examiner relies upon Pisecky for teaching atomization of a liquid while admixing steam in a mixing chamber such that the liquid is pasteurized. Pisecky is directed to a spray drying atomizer wheel which degasifies a liquid composition prior to atomization in order to reduce air inclusion in the final dry product (column 1, lines 1-40; column 2, line 62 to column 3, line 2). However, Pisecky fails to teach or suggest atomization in the mixing chamber, as recited in the subject claims. Instead, Pisecky discloses that first “steam is **mixed** with milk concentrate **in annular chamber 18** and hereby heats the concentrate” (col. 6, lines 30-31, emphasis added), and then “the liquid is flung out in a known manner through ejection apertures **6** and is **atomized in a drying chamber** (not shown) in which the particles of liquid are dried by means of hot air” (col. 6, lines 38-41, emphasis added). Thus, Pisecky clearly teaches atomization in the drying chamber outside of the mixing chamber, and does not teach atomization inside the mixing chamber.

Pisecky is silent with regard to pasteurization or sterilization. Pisecky discloses heating the liquid by mixing with steam, but not in combination with a specific heating time, nor does it teach heating of the liquid while being atomized in the mixing chamber. In the absence of atomization inside the mixing chamber, there is insufficient mixing of steam and liquid within 20 msec in the mixing chamber to heat the liquid sufficiently to accomplish pasteurization or sterilization. If the mixing chamber residence time of the non-atomized steam and liquid mixture of Pisecky is so long that pasteurization/sterilization occurs, heat-damage to any heat-sensitive substances present would likely occur. Similarly, the direct steam injection method of UHT

sterilization has a heating period of 2-5 seconds (please see Attachment A) to allow steam bubbles to condense and distribute heat throughout the liquid, but 2-5 seconds of heating can cause heat-induced flavor damage. Thus, Pisecky does not disclose or suggest a method that both pasteurizes or sterilizes a product and avoids or at least reduces detrimental effects to heat-sensitive substances, let alone a method that atomizes the product with steam in a mixing chamber in which the product resides for about 0.2-20 msec.

Badertscher fails to remedy the deficiencies of Pisecky. Badertscher is directed to sterilization of liquids without drying. Badertscher fails to teach or suggest atomization of liquid and steam in a mixing chamber, and also fails to teach or suggest a residence and thus heating time in the mixing chamber between about 0.2 and 20 msec. Badertscher teaches that the product is kept at the sterilization temperature in a dwell pipe, of which the dimensions determine the duration of the heat treatment, and the product is not cooled until it leaves the dwell pipe (page 3, lines 96-98 and lines 107-109). Badertscher then gives an example of a dwell pipe with a length of 2 meters and a diameter of 35 mm (page 5, lines 10-11). At a rate of injection into the mixing region of 0.2 or 0.3 m/s (Table II), the product would be heated at sterilization temperature for about 6-10 seconds, thus causing greater detrimental effects to heat sensitive substances in the product. Badertscher does not suggest how to sterilize a liquid product within 20 msec, let alone that sterilization would be effected by atomizing the product with steam inside the mixing chamber.

The Examiner relies upon Den Hollander to teach a method of pasteurizing or sterilizing milk in less than one second. But Den Hollander fails to remedy the deficiencies of Pisecky. Den Hollander is also directed to sterilization of liquids without drying. Den Hollander teaches to briefly heat milk in a downflow heater plant wherein the milk is heated to approximately 150 °C in less than a second during free fall (col. 7, lines 25-28). However, Den Hollander does not teach or suggest that sterilization can be accomplished in 20 msec or less, which is 50 times and two orders of magnitude shorter than one second. Den Hollander does not provide any suggestion to reduce residence time in the downflow heater plant to 20 msec or less, nor does it suggest how sterilization could be accomplished in such a short time span.

The Examiner is of the opinion that it is a matter of routine experimentation to minimize residence time in the mixing chamber. Applicant disagrees with this position. At best, the

Examiner's position is similar to an obvious-to-try position, since Den Hollander provides no reasonable expectation of successfully reducing residence times with its method and apparatus. Merely heating a liquid stream by contacting with steam (regardless of whether the liquid is free falling or not) for 20 msec is not sufficient for pasteurization or sterilization. A fundamentally different approach is taken in the process of invention, namely atomizing the product while mixing with steam in a mixing chamber, so that sufficient heat transfer is achieved in about 0.2 to 20 msec in order to pasteurize or sterilize the product. In contrast, Den Hollander teaches that the liquid is introduced into the downflow heater plant as liquid jets which can be very elongated and retain their shape, and that steam condenses on the liquid jets (col. 2, lines 4-8, lines 17-21, line 33). Thus, Den Hollander does not teach or suggest atomization of the product with steam in the mixing chamber, and does not teach or suggest a method capable of sterilizing or pasteurizing a liquid product in about 0.2 to 20 msec.

The Examiner relies upon Scott to teach a spray-dried powder with a primary particle size of 10-60 micrometers (col. 5, lines 4-10). However, as discussed in detail in section B of the previous Office Action response filed on September 5, 2006 and incorporated herein by reference, the skilled artisan would not be motivated to combine Scott with Pisecky because the method of Scott produces hollow sphere particles (col. 5 lines 4-5), whereas the method of Pisecky produces the opposite: a powder with high bulk density and low content of occluded air (abstract). Scott also fails to remedy the deficiencies of Pisecky. Scott does not disclose sterilization or pasteurization of liquids. Scott fails to teach or suggest atomizing a liquid product with steam in a mixing chamber, nor does Scott disclose a retention time of the product in a mixing chamber of about 0.2 to 20 msec. Moreover, Scott teaches particles that are insoluble at a pH greater than 5 (col. 1, lines 58-64). The particles of Scott are therefore not reconstitutible (in water at approximately neutral pH) into a liquid food product suitable for infant consumption. Scott's method teaches cross-linking of proteins in the particles with formaldehyde (col. 5, lines 5-7). The skilled artisan seeking to pasteurize or sterilize a product without altering or damaging its constituents would not be motivated to look to a method that intentionally cross-links and polymerizes proteins. Also, the use of formaldehyde may be acceptable for preparing ruminant feed, but it is not desirable when preparing a food product suitable for infant consumption.

The Examiner relies upon the ehow.com internet printout to disclose steps for dissolving powdered infant formula. However, the ehow.com internet printout cannot be used as prior art to the present application. As shown in the attached web.archive.org internet printout (please see Attachment B), the ehow.com webpage was first published on June 28, 2004. The present application was filed on June 17, 2003, and claims priority from PCT/NL01/00935 filed on December 21, 2001, which claims priority from NL 1016981 filed on December 22, 2000. All of these filing dates precede the ehow.com webpage publication date, therefore the ehow.com internet printout is not prior art.

For at least the foregoing reasons, none of the cited references teaches or suggests that pasteurization or sterilization can be effected within about 0.2 to 20 msec by atomizing a product with steam in a mixing chamber, thereby substantially avoiding heat damage to heat-sensitive substances in the product. In so far as the cited references disclose pasteurization or sterilization, the cited references teach or suggest heating times and/or residence times at least 50 times and two orders of magnitude longer than about 0.2 to 20 msec. The cited references also fail to provide motivation to modify their teachings by atomizing the product with steam in a mixing chamber. Accordingly, a *prima facie* case of obviousness cannot be made, and Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection and allowance of claims 25, 27, 29, 32-34, 37, 40, and 48-52.

B. Any combination of cited references fails to render the claimed invention obvious.

None of the remaining references, alone or in combination, cures the deficiencies of the references discussed above.

Rubens fails to cure the deficiencies of Pisecky, Badertscher, Den Hollander, and Scott. Rubens is directed to a method of cooking/gelatinizing and spray-drying starch (abstract, page 3, lines 17-18). Starch is a polysaccharide, which is one of the heat-sensitive substances (specification page 4, lines 20-24) that Applicant's invention leaves substantially undamaged after pasteurizing or sterilizing the product. Rubens' disclosed method, however, intentionally heat-damages (cooks/gelatinizes) the starch slurry. Thus, Ruben teaches away from and so fails to provide motivation for atomizing a product with steam in a short enough period of time (about 0.2 to 20 msec) to substantially avoid damage to heat-sensitive substances.

Arndt fails to cure the deficiencies of Pisecky, Badertscher, Den Hollander, and Scott. Arndt is directed to methods of blending sweet dairy whey and an isolated, non-animal protein using a specific heat and pressure treatment (col. 2, lines 8-38). Arndt teaches that said ingredients are suspended and then mixed with steam in a holding chamber for about 7 to about 100 seconds (col. 5, lines 44-47). So Arndt fails to teach or suggest a retention time in the mixing chamber of about 0.2 to 20 msec.

Bond fails to cure the deficiencies of Pisecky, Badertscher, Den Hollander, and Scott. Bond is directed to a method for drying paper using superheated steam and cylinders heated by saturated steam (abstract). Bond is not related to methods for pasteurization or sterilization, and certainly fails to teach or suggest atomizing a product in liquid form with steam in a mixing chamber for about 0.2 to 20 msec. The skilled artisan in pasteurization or sterilization or spray-drying would not be motivated to look to Bond because it is in the nonanalogous art field of paper drying.

Hovmand fails to cure the deficiencies of Pisecky, Badertscher, Den Hollander, and Scott. Hovmand is directed to an agglomerating unit which deposits moistened powder on its conical inner surface (abstract). Hovmand is not related to methods for pasteurization or sterilization, and certainly fails to teach or suggest atomizing a product in liquid form with steam in a mixing chamber for about 0.2 to 20 msec.

Johnston fails to cure the deficiencies of Pisecky, Badertscher, Den Hollander, and Scott. Johnston is directed to a method for sterilizing liquids such as milk and milk products (page 1, left column, lines 1-4). Johnston teaches that the product traverses the sterilizing chamber within six seconds, during which time the heat treatment is continued (page 2, left column, lines 65-69, page 3, right column, lines 15-21). Thus, Johnston fails to teach or suggest a retention time in the mixing chamber of only about 0.2 to 20 msec.

Bosund fails to cure the deficiencies of Pisecky, Badertscher, Den Hollander, and Scott. Bosund is directed to a process for preparing a protein isolate from fish material (abstract). Bosund is not related to methods for pasteurization or sterilization, and fails to teach or suggest atomizing a product in liquid form with steam in a mixing chamber for about 0.2 to 20 msec.

For at least the foregoing reasons, the combination of references fails to teach or suggest or provide motivation to combine teachings to arrive at the claimed invention. Accordingly,


Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection and allowance of claims 26, 30, 31, 35, 36, 38, 41-43, and 47.

IV. Conclusion

Having addressed all outstanding issues, Applicant respectfully requests reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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